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10/524,793	10/20/2005	Kenneth M. Evans	XY-Hypodermic-USNP	8305
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CR MILES P.C. 405 Mason Court, Suite 119 Fort Collins, CO 80524			EXAMINER FRITCHMAN, REBECCA M	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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***Detailed Action  
Summary***

This is the Final Office action based on the 10/524793 application RCE attorney response filed on 03/15/2010.

Claims 1-14 & 27 are pending and have been fully considered.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**1. Claims 1-14, & 27 are rejected under 35 U.S.C. 103(a) as being obvious over BUCHANAN in US 6604435 and in further view of NEWTON in US 6230982.**

With respect to Claim 1, BUCHANAN et al. teaches of a method of flow cytometry which focuses on sorting delicate cells, especially living sperm cells(which are obviously from male species of mammals)(column 1, lines 11-18). BUCHANAN et al. also teach injecting fluid into a ribbon flow (which has a central longitudinal axis) through an injection point (column 8, line 62-67 & column 9, lines 1-9). In addition to that, BUCHANAN et al also teaches of a liquid flow cytometer system where a sample is processed into individual droplets prior to being analyzed and sorted (column 5, lines 26-31). Also, BUCHANAN et al. teach of sorting sperm containing drops by the sorting

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device (obviously two or more groups) (column 10, lines 33-37). BUCHANAN et al. do not specifically teach of the adjustable injection point. NEWTON teaches of an adjustable valve for varying the position of injection into a flowing liquid stream, slidably adjusting the position of the valve with respect to the center of the stream (Claim 29). It would have been obvious to modify the method of flow cytometry of BUCHANAN by using the adjustable, slidable fluid dispensing valve of NEWTON in order to adjust the inlet of the cells within the carrier fluid to minimize backflow which results in unwanted contamination of dispersing fluids (NEWTON, column 1, lines 19-23). It would be obvious to one of ordinary skill to provide a built in selection mechanism as this would be automation of a manual method. In re Venner, 120 USPQ 192.

With respect to Claim 2, BUCHANAN et al. teaches of the use of bovine and equine sperm cells which have been stained and sorted by their DNA content (column 15, lines 5-10).

With respect to Claim 3, BUCHANAN et al. teaches of the sample stream being drawn into a thin ribbon by the sheath fluid (column 6, lines 36-37).

With respect to Claim 4, BUCHANAN et al. teaches of sperm cells being buffered in specifically prepared sperm compatible buffer (column 10, lines 41-44). Citrate, phosphate, and HEPES buffer are all well known in the art and would have been obvious to use.

With respect to Claim 5, BUCHANAN et al. teaches of obtaining sperm cells of the male and female bovine and equine species wherein the step of injecting sperm cells into the sheath fluid comprises injecting sperm cells from the selected groups into

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the sheath fluid at an injection point (Claim 10 & 17). It is obvious to one of ordinary skill in chemical analysis to inject the sperm cells of the first and second species at different injection points to allow for differentiation between the species during analysis.

With respect to Claim 6, BUCHANAN et al. teaches of adjusting the injection point by use of a beveled tip where by the preferred amount of beveling is 4 degrees(column 6, lines 40-67, column 7, lines 1-27).

With respect to Claim 7, NEWTON teaches of an adjustable valve for varying the position of injection into a flowing liquid stream, slidably adjusting the position of the valve with respect to the center of the stream (Claim 29). It would have been obvious to modify the method of flow cytometry of BUCHANAN by using the adjustable, slidable fluid dispensing vale of NEWTON in order to adjust the inlet of the cells within the carrier fluid to minimize backflow which results in unwanted contamination of dispersing fluids (NEWTON, column 1, lines 19-23).

With respect to Claim 8, NEWTON teaches of slidably adjusting the position of the valve with respect to the center of the stream (Claim 29). This is equivalent method to the slidable valve and therefore would be considered obvious to one of ordinary skill in the art.

With respect to Claim 9, BUCHANAN et al. teaches of adjusting the injection point by use of a beveled tip where by the preferred amount of beveling is 4 degrees(column 6, lines 40-67, column 7, lines 1-27). BUCHANAN et al. also teaches of varying the size of the nozzle, height and the diameter(column 7, lines 9-15) through

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which the distance between injection points of the sperm cells into the fluid stream would be altered.

With respect to Claim 10, BUCHANAN et al. teaches of adjusting the injection point by use of a beveled tip where by the preferred amount of beveling is 4 degrees( 4 degrees is the optimum for preferred stream resolution)(column 6, lines 40-67, column 7, lines 1-27). BUCHANAN et al. also teaches of varying the size of the nozzle, height and the diameter (column 7, lines 9-15) through which the distance between injection point of the sperm cells into the fluid stream would be altered.

With respect to Claim 11, BUCHANAN et al. teach of adjusting the injection point by use of a beveled tip where by the preferred amount of beveling is 4 degrees( 4 degrees is the optimum for preferred stream resolution)(column 6, lines 40-67, column 7, lines 1-27). BUCHANAN et al. also teach of the sample stream being drawn into a thin ribbon(due to the beveling) by the sheath fluid, the resulting change in flow condition causing a corresponding orientation of the sample material (column 6, lines 35-39).

With respect to Claim 12, BUCHANAN et al. teach of et al. teach of adjusting the injection point by use of a beveled tip where by the preferred amount of beveling is 4 degrees( 4 degrees is the optimum for preferred stream resolution)(column 6, lines 40-67, column 7, lines 1-27). BUCHANAN et al. also teach of the sample stream being drawn into a thin ribbon(due to the beveling) by the sheath fluid, the resulting change in flow condition causing a corresponding orientation of the sample material (column 6, lines 35-39).

With respect to Claim 13, BUCHANAN et al. teaches of sorting delicate cells, especially sperm cells (column 1, lines 16-17).

With respect to Claim 14, BUCHANAN et al. teaches of sorting delicate cells, especially sperm cells (column 1, lines 16-17). BUCHANAN et al. also teaches of the sperm containing drops being sorted by the sorting device and collected by the sperm-compatible collecting system wherein the X or Y chromosome bearing sperm may be used for insemination (column 10, lines 50-57).

With respect to Claim 27, Examiner takes notice of the equivalence of a slidably adjustable valve (slidable engagement between particle injector and nozzle body) to a key stop mated with a nozzle body in adjusting, selectively and variably the injection point. This is also evidenced in applicants arguments dated 04/29/2009, (page 1, paragraph 2).

### ***Response to Arguments***

Applicant's arguments filed 03/15/2010 have been fully considered but they are not persuasive.

In response to applicant's argument that NEWTON is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, NEWTON teaches of an adjustable valve for varying the position of injection into a

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flowing liquid stream, slidably adjusting the position of the valve with respect to the center of the stream (Claim 29). As applicant points out, the function of the NEWTON device is to disperse tiny droplets or micelle like moieties prior to integrating the flow stream in order to thoroughly mix and precisely meter small amounts of fluidic substances into the flowing stream. In the instant invention, tiny droplets of sperm cells are being injected into a fluid stream for flow cytometry. Therefore, both NEWTON and the instant invention are analogous art due to the fact that since both deal with the injection of droplets into fluid streams.

Also, NEWTON does teach of slidably adjusting the position of the valve with respect to the center of the stream (Claim 29). This would be capable of increasing the resolution of particles the same way as in the instant invention (the position of the valve is what increases resolution). Also, the examiner is somewhat confused about what reference the applicant is referring to when they mention "Buckley" (Page 11, paragraph 3, applicant's remarks/arguments).

With respect to the argument that BUCHANAN/NEWTON combination doesn't teach all of the elements of the claimed invention:

NEWTON does in fact teach of slidably adjusting the position/location of the valve with respect to the center of the stream (this can mean radial or axial adjustment) (adjustably varying the axial location of injection point along the central longitudinal axis) (Claim 29).

With respect to Claim 5, the examiner apologizes for the incorrect use of the term inherent. This was merely a typo & the examiner meant for this to read "obvious" which



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should be clear since Claim 5 was rejected under 103(a). Also, it is obvious to one of ordinary skill in chemical analysis to inject the sperm cells of the first and second species at different injection points to allow for differentiation between the species during analysis.

With respect to Claim 6, applicant seems to be arguing that the micelles or droplets used in NETWON are not "particles". In the examiner's understanding, a particle is just a small bit of matter & therefore micelles are "particles".

With respect to Claims 11 & 12, see arguments above with respect to the non-analogous art argument.

With respect to the argument that there is lack of motivation to combine references:

As stated above, NEWTON does in fact teach of slidably adjusting the position/location of the valve with respect to the center of the stream (this can mean radial or axial adjustment) (adjustably varying the axial location of injection point along the central longitudinal axis) (Claim 29). This (the placement of an axially adjustable valve) would not change the principal of operation.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REBECCA FRITCHMAN whose telephone number is (571)270-5542. The examiner can normally be reached on Monday- Friday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kim, Vickie can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Krishnan S Menon/

Primary Examiner, Art Unit 1797

R.F.